II. Request for Continued Examination

This response to the Office Action is filed with a request for continued examination ("RCE") after receipt by applicants of a final office action and with payment of the required fee. Hence the RCE is appropriate and the examiner is asked to withdraw the finality of the Office Action and enter this response.

III. Claims Cancelled

Applicants hereby cancel claims 36, 40-41, 48-50, 53-54, 57-60 and 68-81, without prejudice to further prosecution at a later date.

The pending claims are therefore the twenty one claims 35, 37-39, 42-47, 51-52, 55-56 and 61-67.

IV. The Section 103(a) Rejection Over Wong

The Office Action rejected claims 35-81 under 35 U.S.C. section 103(a) as being unpatentable over Wong et al (U.S. patent 5,869,079. Respectfully, the rejection is in error and should be withdrawn.

As stated by the Office Action, the Wong reference discloses a PLGA implant containing dexamethasone. The Office Action states in numbered paragraph 7. on page 3 of the Office Action that since the instant claims are product claims an intended use does not provide a patentable distinction because "if a prior art structure (i.e. Wong) is capable of performing the intended use, then it meets the claim." (this statement is also repeated on page 6, numbered paragraph 12. of the Office Action). It is also noted by page 4, numbered paragraph 8. of the Office Action that while Wong does not teach the exact claimed formulations and rates of release, these claimed differences are obvious since Wong suggests changing the size and form of the implant and the Office Action cites to columns 7-8 of Wong for this point, noting that a person of ordinary skill would have been motivated to make such modification, to thereby arrive at the claimed invention.

In light of these comments in the Office Action applicants have amended the claims to limit the claims to an implant which clearly distinguishes over the implant disclosed by Wong. As explained below, the prior art structure of Wong is not capable of performing the intended use of the claimed subject matter, and therefore the amended claims are patentable over Wong.

The claims have been amended to add the following limitations to the claims:

1. "the implant being an extruded filament" (All Claims). This new claim limitation is supported by at least page 26, paragraph [0089] of Example 6 of the specification ("...filaments extruded...The resulting filaments...")

2. "the implant having a weight between about 500 μg and about 1100 μg" (All Claims). This new claim limitation is supported by at least page 18, paragraph [0062] of Example 1 of the specification ("...900-1100 μg..."), and by page 26, paragraph [0089] of Example 6 of the specification ("...500μg and 1000 μg...").

3. "the implant delivers at least about 20% of the agent within about 20 days in vitro". (Claims 35, 37-38, 42-47, 51 This new claim limitation is supported by at least: (1) Table 6 for replicate 1 on page 26 of the specification (note that by day 20 just over 30% of the agent had been released from the implant in vitro; (2) Table 6 for replicate 2 on page 27 of the specification (note that by day 20 almost exactly 20% of the agent had been released from the implant in vitro; (3) Table 7 for replicate 1 on page 28 of the specification (note that by day 20 over 23% of the agent had been released from the implant in vitro; (4) Table 7 for replicate 2 on page 28 of the specification (note that by day 20 just over 19% of the agent had been released from the implant in vitro.

4. "the implant delivers at least about 30% of the agent within about 20 days in vitro". (Claims 39, 52, 55-56 and 61-67). This new claim limitation is supported by at least Table 6 for replicate 1 on page 26 of the specification (note that by day 20 just over 30% of the agent had been released from the implant in vitro.; (2) Table 6 for replicate 2 on page 27 of the specification (note that by day 20 al

As noted by the last sentence of numbered paragraph 7., on page 4 of the Office Action: "Wong et al. also teach that the size and form of the implant can be used to control the rate of release, period of treatment , and drug concentration (column 7, lines 52-54)". Note that Wong then immediately states: "Larger implants will deliver a proportionately larger dose, but depending on the surface to mass ratio, may have a slower release rate."

All claims in the instant application have the limitation "without an added release modifier". Only (the first part of) Example 1 of Wong sets forth an implant which does not have a release modifier. The implants in Example 1 of Wong are extruded filaments weighing 100-120 μg.

Example 1 at column 8, lines 44-46 of Wong states that the drug released very slowly from the small extruded filaments. Thus, as shown by FIG 1A of Wong after 20 days in vitro only about 10% of the drug had been released.

An implant shaped as a sheet, film, circular disc or plaque (see column 7, lines 39-40 of Wong) has a high surface are to mass ratio, as compared to an implant which is shaped as a filament (i.e. a rod shaped implant). As easily understood, an implant will release more drug if it has a high surface to mass ratio, as compared to an implant which has a lower surface to mass ratio (other factors [such as the absence of a release modifier] being held constant)

Thus, Wong found that small (100 ug to 120 μg) filament shaped implants which do not have a release modifier release drug slowly (column 8, lines 44-48), and Wong states that although a larger implant can deliver more drug, it will have a slower release rate unless the surface to mass ratio is increased (i.e. change the shape of the implant form a filament to a sheet or film shape) (column 7, lines 53-56 of Wong).

Clearly, therefore Wong does not teach or suggest that a larger implant with the same shape ("filament") made in the same way ("extruded") and which therefore has the same surface to mass ratio, will release drug faster than a smaller extruded filament implant. In fact, Wong clearly teaches away from the claims as amended, which are limited to an extruded filament implant which releases at least 20% of the drug after 20 days in vitro. Wong states or at least strongly implies that to get such a faster drug release with a larger implant one must either use an implant which has a higher surface area to mass ratio, as

compared to a filament shaped implant, or (as done by Wong) use the same filament shaped implant but add one or more release modifiers (see Wong column 8, line 48, continuing to column 10.

For these reasons, the rejection over Wong should be withdrawn. See also *In re Soni*, 34 USPQ2d 1684-1692 (Fed. Cir. 1995) (reversing the Board decision affirming examiner's rejection of certain claims on the basis that once unexpected results are established, in the absence of contrary evidence, unexpected results successfully overcome the prima facie case of obviousness.

V. The Section 103(a) Rejection Over Wong and Guo

The Office Action rejected claims 48-50 and 68-70 under 35 U.S.C. section 103(a) as being obvious over the combination of Wong (U.S. patent 5,869,079) and Guo (U.S. patent 6,217,8951).

Claim 48-50 and 68-70 have been cancelled. Hence the rejection should be withdrawn.

VI. Conclusion

All issues raised by the Office Action have been addressed. Examination and allowance of claims 35, 37-39, 42-47, 51-52, 55-56 and 61-67 is requested.

Respectfully submitted,

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CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

I hereby certify that this Transmittal Letter, Response to Office Action and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date October 12, **2005** in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV616153408US addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Adriane Giberson
Name of person mailing paper

Date: October 12, 2005

Signature of person signing paper